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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,069	BRASLAWSKY ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that this office action sets forth a tiered restriction/election requirement, wherein multiple elections are applicable to Inventions I-V (see items 2-5 below).

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-18, drawn to a method of treating a neoplastic disorder with a dimeric antibody, classified in class 424, subclass 138.1.

   II. Claims 1-14 and 17-19, drawn to a method of treating an immune disorder with a dimeric antibody, classified in class 424, subclass 133.3.

   III. Claims 29-35, 38-40 and 20-28, drawn to a dimeric antibody that binds an autoantigen, classified in class 530, subclass 387.3

   IV. Claims 29-34, 36-40 and 20-28, drawn to a dimeric antibody that binds a tumor associated antigen, classified in class 530, subclass 388.85.

   V. Claims 41-50, drawn to a method of making dimeric antibodies, classified in class 435, subclass 69.6.

2. For each of invention sets I, II, IV and V above, restriction to one of the following is also required under 35 U.S.C. 121. Therefore, election is required of one of inventions I, II, IV and V and one of inventions (A)-(V).

(A) CD2.
(B) CD3.
(C) CD5.
(D) CD6.
(E) CD7.
(F) MAGE-1.
(G) MAGE-3.
(H) MUC-1.
(I) HPV 16.
(J) HPV E6
(K) HPV E7.
(L) TAG-72.
(M) CEA.
(N) L6 Antigen.
(O) CD19.
(P) CD20.
(Q) CD22.
(R) CD37.
(S) CD52.
(T) HLA-DR.
(U) EGF Receptor.
(V) HER2 Receptor.

3. For invention set I above, restriction to one of the following is also required under 35 U.S.C. 121. Thus, should applicant elect Group I, election is required of one of inventions (A)-(V) and one of inventions (a)-(w).

(a) Relapsed Hodgkin's disease.
(b) Resistant Hodgkin's disease high grade.
(c) Low grade and intermediate grade non-Hodgkin's lymphomas.
(d) B cell chronic lymphocytic leukemia (B-CLL).
(e) Lymphoplasmacytoid lymphoma (LPL).
(f) mantle cell lymphoma (MCL).
(g) follicular lymphoma (FL).
(h) diffuse large cell lymphoma (DLCL).
(i) Burkitt's lymphoma (BL).
(j) AIDS-related lymphomas.
(k) monocytic B cell lymphoma.
(l) angioimmunoblastic lymphoadenopathy.
(m) small lymphocytic.
(n) follicular, diffuse large cell.

(o) diffuse small cleaved cell.
(p) large cell immunoblastic lymphoblastoma.
(q) small, non cleaved.
(r) Burkitt's.
(s) non-Burkitt's.
(t) follicular, predominanatly large cell.
(u) follicular, predominantly small cleaved cell.
(v) follicular, mixed small cleaved and large cell lymphomas.
(w) a single neoplastic disorder of the instant disclosure (page 46, for example).

4. For invention set II above, restriction to one of the following is also required under 35 U.S.C. 121. Thus, should applicant elect Group II, election is required of one of inventions (A)-(V) and one of inventions 1-150 (i.e., immune disorder) disclosed on pages 47-48 of the instant disclosure or a single immune disorder supported by the instant disclosure.

5. For invention set III above, restriction to one of the following is also required under 35 U.S.C. 121. Thus, should applicant elect Group III, election is required of one of inventions (i)-(iii).

(i) allergen
(ii) alloantigen and xenoantigen
(iii) a single autoantigen supported by the instant disclosure

6. Claims 1 and 19 link inventions I-II, (A)-(V), (a)-(w) and 1-150. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 19. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such

claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Claim 29 links inventions III and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 29. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Claim 35 links inventions (i)-(iii). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 35. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions

shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions (A)-(V) are structurally and functionally different; an antibody that binds CD2 would not bind molecules (B)-(V), for example.

Inventions (a)-(w) are different because their etiologies and therapeutic endpoints differ.

Inventions 1-150 are physiologically different and differ in the method objectives, method steps, reagents used and endpoints.

Inventions (i)-(iii) are structurally and functionally different and an antibody to one would not bind the others.

Inventions of Groups III and IV represent separate and distinct products, which have different functions and different effects. The dimeric antibody of Group III binds an autoantigen and the dimeric antibody of Group IV does not. Likewise, the dimeric antibody of Group IV binds a tumor-associated antigen and the dimeric antibody of Group III does not. The examination of both groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups III and IV are patentably distinct.

The methods of Inventions I, II and V differ in the method objectives, method steps, parameters and in the reagents used. Invention I recites a method of treating a neoplastic disorder with a dimeric antibody; Invention II recites a method of treating an immune disorder with a dimeric antibody; Invention V recites a method of making dimeric antibodies. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, inventions I, II and V are separate and distinct in having different method objectives, method steps and different endpoints and are patentably distinct.

Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the dimeric

antibody of Group IV can be used in a materially different method such as to purify the antigen in addition to the materially different method of Group I, which differ in the method objectives, method steps and endpoints.

Inventions V and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a dimeric or tetrameric enzyme, in addition to the materially different antibody of Group III or the materially different antibody of Group IV.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER